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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,574	06/25/2003	James Roy Maxwell	1391/1558	6293
28455	7590	07/26/2005	EXAMINER	
WRIGLEY & DREYFUS 28455			GRAFFEO, MICHELLE	
BRINKS HOFER GILSON & LIONE				
P.O. BOX 10395			ART UNIT	
CHICAGO, IL 60610			PAPER NUMBER	
			1614	

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/607,574	Applicant(s) MAXWELL ET AL.	
	Examiner Michelle Graffeo	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-70 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/10/04</u> + <u>6/26/03</u> | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Status of Action

Claims 1-70 are pending and examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3-8, 17-20, 30-31, 35-36, 43-45 and 47-49 are rejected under 35

U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For exemplification purposes, claim 3 recites "the maltodextrin comprises about 5wt.% to about 60wt.% of the edible film.". Presently, the term "comprises" is interpreted to mean "to include especially within a particular scope" or "to be made up of". Therefore, it is unclear how the maltodextrin can be made up of 5wt.% to about 60wt.% of the edible film when claim 3 depends from claim 2 which depends from claim 1 which teaches that the edible film itself is made up of the maltodextrin.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7-17, 19-22, 24, 27-35, 37-43, 46-68 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,971,806 to Cherukuri et al. in view of US Patent Application No. 2003/0224090 to Pearce et al.

Cherukuri et al. teach a chewing gum composition and methods of making same comprising:

- cinnamic aldehyde (see col 7 lines 11-12) present in an amount of from 0.05 to 3% (see col 7 line 45),
- up to about 90% maltodextrin (see col 5 lines 35-40),
- up to about 30% fillers (see col 5 lines 26-31 and col 4 lines 57-59) such as wood (see col 4 line 35), calcium carbonate, magnesium silicate, tricalcium phosphate and dicalcium phosphate (see col 4 lines 64-66),

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- hydrocolloids such as alginates (of which one skilled in the art would find sodium and calcium to be obvious species), starch, pectin, gum arabic (see col 8 lines 15-21) wherein the starch pectin and gum arabic can be present in amounts of 0.1 to 12% (see col 8 line 45) and carrageenan (see col 5 line 22),
- a medicament (see col 9 lines 55-end) such as aspirin, fluorides and calcium carbonate (see col 10 Lines 1-6), food acids such as citric, adipic and tartaric acid (see col 5 line 25),
- softening agents (see col 5 line 15) such as propylene glycol present in amounts up to about 30% (see col 4 lines 45-63),
- an effective amount of a colorant (see col 5 line 3),
- flavoring agents (see col 6 line 59) such as oils (spearmint) and synthetic flavoring oils (see col 6 lines 65-end) or menthol (see col 7 line 8) present in an amount of from 0.05 to 3% (see col 7 lines 38-45), and,
- emulsifiers such as lecithin (see col 5 line 20).

Cherukuri et al. do not recited an edible film per se.

Pearce et al. teach an edible film comprising fillers, (see paragraph 41), hydrocolloids, (see paragraph 28), flavoring (see paragraph 57), color (see paragraph 133) and cinnamaldehyde (see paragraph 63).

Cherukuri et al. do not teach per se a method of delivering a certain amount of cinnamaldehyde to the oral cavity. Nonetheless, one skilled in the art would find it obvious to routinely optimize the amount of cinnamaldehyde that is added and

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subsequently released into the oral cavity. Cherukuri et al. expressly suggest that the amount of flavoring "employed is normally a matter of preference subject to such factors as flavor type, individual flavor, gum base and strength desired. Thus, the amount may be varied in order to obtain the result desired in the final product. Such variations are within the capabilities of those skilled in the art without the need for undue experimentation." (see col 7 lines 38-44).

Cherukuri et al. do not teach a method for reducing the number or activity of bacterial in the oral cavity per se. Nonetheless, Cherukuri et al. described a composition comprising the same ingredients as those in the instant claims, wherefore; the composition must have the same functional properties. Therefore, absent evidence to the contrary, use of the composition described in Cherukuri et al. necessarily reduces the number or activity of bacteria in the oral cavity.

One of skill in the art would be motivated to combine Cherukuri et al. with Pearce et al. and as combined would make obvious the invention as claimed above. Both references are directed to edible compositions and contain the same ingredients, all of which are well known in the art. One skilled in the art would find it obvious, given the same set of ingredients to make both a film and a gum as described above. Moreover, one will necessarily make the claimed composition by employing the ingredients claimed in the amounts claimed. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

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Claims 6, 18, 36, 44-45 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,971,806 to Cherukuri et al. as applied above in view of US Patent Application No. 2003/0224090 to Pearce et al. as applied above and further in view of WO 99/18940 to Bush Boake Allen Inc.

Cherukuri et al. do not teach a composition comprising about 20-30% of a hydrocolloid; 6-25% cinnamaldehyde; 10-15% a flavoring agent; or heating the aqueous solution to a temperature of 40-60°C.

The WO 99/18940 reference teaches processed starches present in an amount up to about 60% (see page 17 line 31), flavoring agent/malodor counteractant such as cinnamic aldehydes (see page 1 lines 25-end) present in an amount of from 0.0001 to 10% (see page 9 lines 4-9), and a process wherein the aqueous mixture was heated preferably from about 40-70°C.

One skilled in the art would be motivated to combine WO 99/18940 with Cherukuri et al. and Pearce et al. WO 99/18940 is directed to an oral vehicle such as chewing gum comprising the traditional ingredients such as fillers (see page 15 lines 20-26), hydrocolloids (see page 17 line 32), maltodextrin and sweeteners (see page 17 line 32 as well). One skilled in the art would be motivated to use the process of making the oral vehicle as well as any variations of ingredients as described in WO 99/18940 because the ingredients are the same and traditional in the art. Moreover, one skilled in the art would expect success using the method described in WO 99/18940 particularly since the ingredients are the same. Thus, the claimed invention was within the ordinary

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skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,971,806 to Cherukuri et al. as applied above in view of US Patent Application No. 2003/0224090 to Pearce et al. as applied above and further in view of US Patent No. 5,487,902 to Andersen et al.

Cherukuri et al. do not disclose a composition comprising a medicament comprising zinc gluconate or triclosan for example. Andersen et al. teach a chewing gum comprising triclosan and zinc gluconate (see col 9 lines 29 and 39).

One of skill in the art would be motivated to combine Andersen et al. with Cherukuri et al. Both references are directed to chewing gums containing traditional ingredients. Moreover Cherukuri et al. teach that medicaments can be added to the composition and teach that the list provided is non-limiting (see col 9 lines 55-end and continuing in col 10 lines 1-6). One of skill in the art would find it obvious to combine the two chewing gum references and include the medicaments in Andersen et al. into the invention of Cherukuri et al. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Claim 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,971,806 to Cherukuri et al. as applied above in view of US Patent

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Application No. 2003/0224090 to Pearce et al. as applied above and further in view of
US Patent No. 1,056,212 to Puetzer et al.

Cherukuri et al. do not disclose a composition comprising a medicament comprising urea with a particular example. Cherukuri et al. teach in col 10 line 2 that antacids can be included in the composition. Puetzer et al. is cited to provide an example of an antacid containing urea.

No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

15 July 2005

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